4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, and 558

[Docket No. FDA-2012-N-0002]

New Animal Drugs; Change of Sponsor's Address; Monensin; Spinosad; Tilmicosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) during August 2012 and to reflect a change of sponsor's address for Baxter Healthcare Corp. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect original and supplemental approval actions during August 2012, as listed in table 1 of this document. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the Center for Veterinary Medicine FOIA Electronic Reading Room. FOI Summaries may be found listed by application number at: http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/default.htm. Environmental assessments and findings of no significant impact may be found listed by the established name of the active pharmaceutical ingredient at: http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/ucm300656.htm.

Also, Baxter Healthcare Corp., 95 Spring St., New Providence, NJ 07974, has informed FDA of a change of address to One Baxter Pkwy., Deerfield, IL 60015. Accordingly, the Agency is amending the regulations in 21 CFR 510.600(c) to reflect this change.

Table 1.-Original and Supplemental NADAs Approved During August 2012

NADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
141-343	Elanco Animal Health, A Division of Eli	PULMOTIL 90 (tilmicosin phosphate) plus	Original approval for use in two-way, combination drug type	558.355 558.618	yes	CE[1]

NADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
	Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285	RUMENSIN 90 (monensin) Type A medicated articles	B and type C medicated feeds for cattle fed in confinement for slaughter			
141-277	Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285	COMFORTIS (spinosad) Chewable Tablets	Supplemental approval for use in cats to kill fleas and for the prevention and treatment of flea infestations (Ctenocephalides felis) for 1 month on cats and kittens 14 weeks of age and older and 2 pounds of body weight or greater	520.2130	yes	CE[1]

[1]The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 520

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, and 558 are amended as follows:

PART 510--NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. In §510.600, in the table in paragraph (c)(1), revise the entry for "Baxter Healthcare Corp."; and in the table in paragraph (c)(2), revise the entry for "010019" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Baxter Healthcare Corp., One Baxter Pkwy., Deerfield, IL 60015	010019
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
010019	Baxter Healthcare Corp., One Baxter Pkwy., Deerfield, IL 60015
* * * * *	

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

4. Revise § 520.2130 to read as follows:

§ 520.2130 Spinosad.

(a) Specifications. Each chewable tablet contains 90, 140, 270, 560, 810, or 1620 milligrams (mg) spinosad.

(b) Sponsor. See No. 000986 in § 510.600 of this chapter.

(c) Special considerations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) Conditions of use--(1) Dogs--(i) Amount. Administer tablets once a month at a recommended minimum dosage of 13.5 mg per pound (30 mg per kilogram) of body weight.

(ii) Indications for use. To kill fleas and for the prevention and treatment of flea infestations (Ctenocephalides felis) for 1 month on dogs and puppies 14 weeks of age and older and 3.3 pounds of body weight or greater.

(2) Cats--(i) Amount. Administer tablets once a month at a minimum dosage of 22.5 mg per pound (50 mg per kilogram) of body weight.

(ii) Indications for use. To kill fleas and for the prevention and treatment of flea infestations (C. felis) for 1 month on cats and kittens 14 weeks of age and older and 2 pounds of body weight or greater.

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

5. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

6. In § 558.355, redesignate paragraph (f)(8)(iv) as paragraph (f)(8)(v); and add new paragraph (f)(8)(iv) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(8) * * *

(iv) Tilmicosin alone or in combination as in § 558.618.

* * * * *

7. In § 558.618, remove and reserve paragraph (c)(3)(ii); and revise paragraph (e) to read as follows:

§ 558.618 Tilmicosin.

* * * * *

(e) * * *

(1) Swine--

Tilmicosin phosphate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 181 to 363		Swine: For the control of swine respiratory disease associated with Actinobacillus pleuropneumoniae and Pasteurella multocida	Feed continuously as the sole ration for 21-day period, beginning approximately 7 days before an anticipated disease outbreak. The safety of tilmicosin has not been established in male swine intended for breeding purposes. Swine intended for human consumption must not be slaughtered within 7 days of the last treatment with this drug product.	000986
(ii) [Reserved]				000986

(2) Cattle--

Tilmicosin phosphate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 568 to 757		Beef and nonlactating dairy cattle: For the control of bovine respiratory disease	Feed continuously for 14 days to provide 12.5 milligrams/kilogram/head/day. The	000986

		(BRD) associated with Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni in groups of beef and nonlactating dairy cattle, where active BRD has been diagnosed in at least 10 percent of the animals in the group	safety of tilmicosin has not been established in cattle intended for breeding purposes. This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk. This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in preruminating calves. Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product.	
(ii) 568 to 757	Monensin, 5 to 40	Cattle fed in confinement for slaughter: For improved feed efficiency; and for the control of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni in groups of cattle fed in confinement for slaughter, where active BRD has been diagnosed in at least 10 percent of the animals in the group.	Feed continuously for 14 days to provide 12.5 milligrams tilmicosin/kilogram/head/day. The safety of tilmicosin has not been established in cattle intended for breeding purposes. This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk. This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in pre-ruminating calves. Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product. See § 558.355(d) of this chapter.	000986
(iii) 568 to 757	Monensin, 10 to 40	Cattle fed in confinement for slaughter: For prevention and control of coccidiosis due to Eimeria bovis and E. zuernii; and for the control of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni in groups of cattle fed in confinement for slaughter, where active BRD has been diagnosed in at least 10 percent of the animals in the group.	Feed continuously for 14 days to provide 12.5 milligrams tilmicosin/ kilogram/head/day. The safety of tilmicosin has not been established in cattle intended for breeding purposes. This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk. This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in pre-ruminating calves. Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product. See § 558.355(d) of this chapter.	000986

Dated: September 28, 2012

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Director,

Center for Veterinary Medicine.

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